

JUST RIGHT 5000- 1.1% sodium fluoride toothpaste gel, dentifrice Elevate Oral Care

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Just Right 5000 - Candy Apple

OTC - ACTIVE INGREDIENT SECTION

Sodium Fluoride 1.1% Anticavity toothpaste

INDICATIONS & USAGE SECTION

helps protect against cavities

WARNINGS SECTION

Keep out of reach of children under 6 years of age: if more than used for brushing is accidentally swallowed, get medical help or contact a poison control center right away.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children under 6 years of age:

INSTRUCTIONS FOR USE SECTION

Directions: *adults and children 2 years and older: wet a toothbrush and pump once to apply a pea-sized (~0.25 gram) amount of toothpaste onto a toothbrush * brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician. * to minimize swallowing, only pump once to dispense a pea-sized amount for children under 6 years. * supervise children's brushing until good habits are established. * children under 2 years: ask dentist or physician.

INACTIVE INGREDIENT SECTION

Inactive ingredients; Sorbitol, Water, Xylitol, Glycerin, Hydrated silica, PEG-8, Caramel Apple Flavor, Sodium Lauryl Sulfate, Xanthan Gum, Potassium Phosphate, Sodium Benzoate, Sodium Saccharin, Mica, FD&C Red 40

OTC - QUESTIONS SECTION

Questions? 1-877-866-9113 or visit our website at www.elevateoralcare.com

OTC - PURPOSE SECTION

Helps protect against Cavities

DOSAGE & ADMINISTRATION SECTION

Directions: *adults and children 2 years and older: wet a toothbrush and pump once to apply a pea-sized (~0.25 gram) amount of toothpaste onto a toothbrush * brush


thoroughly after meals or at least twice a day or use as directed by a dentist or physician. * to minimize swallowing, only pump once to dispense a pea-sized amount for children under 6 years. * supervise children's brushing until good habits are established. * children under 2 years: ask dentist or physician.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

57511-0122-8

Just Right™ 5000

1.1% Sodium Fluoride



**Candy Apple
FLAVOR**

**6 Month
Metered
Dose
System**

**With 10%
Xylitol**

Rx Only

**Net Wt.
3.4 oz
(97 g)**

INDICATIONS: Topical fluoride for use in the prevention of dental caries.

ACTIVE INGREDIENT: Sodium Fluoride 1.1% (5000 ppm fluoride)

DIRECTIONS FOR USE: This prescription toothpaste is recommended for adults and children 6 years of age and older. Use daily in place of a conventional toothpaste. Follow these instructions unless otherwise instructed by a dentist or physician.

1. Apply one pump (0.25 g) of Just Right™ Toothpaste to toothbrush and brush teeth thoroughly for two minutes.
2. After brushing, adults should spit, but not rinse. Children should spit after brushing and then rinse mouth thoroughly with water.

Just Right toothpaste can be used in place of your regular toothpaste based on the recommendation of your dentist or physician.

WARNINGS: Do not swallow. Keep out of reach of children under 6 years of age. Read all instructions and prescribing information before using this product. Do not freeze or expose to extreme heat.

Elevate Oral Care, West Palm Beach, FL 33411.
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JUST RIGHT 5000

1.1% sodium fluoride toothpaste gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57511-0122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	1.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	

PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN (UNII: FST467XS7D)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	blue	Score	
Shape	ROUND	Size	
Flavor	APPLE (and Caramel)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57511-0122-8	97 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2020	11/01/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2020	11/01/2023

Labeler - Elevate Oral Care (002863526)

Registrant - Elevate Oral Care (002863526)

Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	repack(57511-0122)